# 14. THERMOMETER (DATA LOGGER) POLICY

## Montana VFC Thermometer Requirements

The CDC and the Montana Immunization Program require VFC providers to have a certified calibrated, continuously monitoring thermometer in each VFC vaccine storage unit. The Montana Immunization Program supplies thermometers to VFC providers in the state. (Due to budget constraints, the State does not supply thermometers to birthing hospitals and pharmacies at this time.)

#### Definitions:

- Certified Calibrated A thermometer that has a certificate stating it has been tested and calibrated as
  accurate against NIST or ASTM measurement standards within the timeframe recommended by the
  manufacturer.
- **Continuously Monitoring** A thermometer that measures and permanently records temperatures on a predetermined schedule so that the data can be reviewed and permanently archived for three years.

### State-Supplied Thermometers – Data Loggers

The Montana Immunization Program provides certified calibrated, continuously monitoring Data Loggers to all VFC providers in Montana, with the exception of birthing hospitals and pharmacies. Data Loggers are electronic thermometers that continuously record and store temperature readings and indicate through a warning light when out-of-range temperatures that threaten vaccine have been encountered. Data Loggers interface with a computer so that data can be removed and saved.

#### **Immunization Program Responsibilities**

- The Immunization Program supplies Data Loggers free-of-charge to VFC providers in the state (with the
  exception of birthing hospitals and pharmacies and dependent upon budget and supply). Each Data
  Logger comes with:
  - Certificate of calibration
  - Acrylic stand
  - Extra battery
  - Software for controlling the unit and saving data.
- If a provider chooses to supply their own certified calibrated, continuously monitoring thermometer (as
  defined above), the Immunization Program must approve the thermometer and issue a memo exempting
  the provider from using a State-supplied Data Logger.
- The Montana Immunization Program and the Data Logger supplier provides training, technical support, and written instructions for using the Data Loggers.
- The Montana Immunization Program facilitates an annual recalibration program for State-supplied Data Loggers at the provider's expense (terms of recalibration may change year to year).

### **Provider Responsibilities**

- All VFC providers are required to use the State-supplied Data Loggers in each VFC vaccine storage unit unless they have a thermometer that meets the VFC requirements as defined above.
- Birthing hospitals and pharmacies must supply their own thermometers that meet VFC requirements. Contact the Immunization Program for information on qualified thermometers.
- Even with continuously recording temperature monitoring, <u>providers still must manually log temperatures twice daily (see Section 13, page 49 Temperature Monitoring).</u> If the provider has centralized temperature monitoring that does not included readable temperature displays, then the temperature data must be reviewed twice daily.
- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software.
- Providers are responsible for replacing broken or malfunctioning Data Loggers with an equivalent unit.
- After the first year, providers are responsible for Data Logger yearly calibration. Re-calibration costs
  approximately 50\$/unit and includes a replacement battery and a loaner for use while the unit is being recalibrated (terms of recalibration subject to change).
- Providers must have an emergency backup thermometer on hand in the event that the Data Logger breaks or malfunctions. Backup thermometers must be working and reliable but are not required to be certified calibrated or continuously monitoring.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the State.

In the routine use of Data Loggers, providers must:

- Use the provided software to setup and activate each Data Logger prior to first use.
- After activation, properly place a Data Logger in each VFC vaccine storage unit.
- Check and log the temperature readout and the color of the out-of-range light twice daily. Temperature
  logging can be on paper (logs provided at <a href="www.immunization.mt.gov">www.immunization.mt.gov</a>) or through imMTrax, the Montana
  immunization information system.
- At the end of every month (prior to reconciling inventory and ordering vaccine) download, review, and save Data Logger data for the previous month. Then enter cold chain data into imMTrax (See Section 15, page 56 for more information on managing cold chain data in imMTrax). Save monthly Data Logger data and paper temperature logs (if used) for three years.
- If out-of-range temperatures that threaten vaccine are encountered, immediately obtain a Vaccine Incident Report, follow steps 1–6, and call the Immunization Program (444-5580).
- Make Data Logger data and temperature logs available for review during VFC site visits from the Montana Immunization Program.

See the *Montana VFC Data Logger Instruction Manual* for specific details on setting up and using your Data Logger. A copy is available on our website at <a href="https://www.immunization.mt.gov">www.immunization.mt.gov</a> under the "VFC" link.